UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

DOLORES MCFADDEN-BROWN, Plaintiff, v. BOSTON SCIENTIFIC CORPORATION, Defendant.	Case No. 2:17-CV-06552-JMA-AYS Hon. Joan M. Azrack

MEMORANDUM OF LAW IN SUPPORT OF BOSTON SCIENTIFIC CORPORATION'S MOTION TO DISMISS

Dated: August 10, 2018

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Pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, defendant Boston Scientific Corporation ("Boston Scientific"), respectfully moves to dismiss the March 9, 2018, First Amended Complaint (the "Amended Complaint") of plaintiff Dolores McFadden-Brown ("Plaintiff").

INTRODUCTION

The Amended Complaint is the second complaint filed by Plaintiff regarding her 2008 implantation with Boston Scientific's Greenfield™ Vena Cava Filter (the "Greenfield Filter"). As in her original complaint, Plaintiff asserts 12 causes of action under New York law—strict liability (manufacturing defect, design defect and failure to warn), negligence, breach of warranty (express and implied), fraudulent misrepresentation and concealment, negligent misrepresentation, violation of Sections 349 and 350 of the New York General Business Law ("GBL"), and punitive damages. Each of the 12 claims is riddled with deficiencies and lacks plausible allegations of any defects in the manufacture, design, or warnings of her Greenfield Filter. A collection of formulaic recitations, void of specificity, is all that the Amended Complaint provides. Accordingly, the Amended Complaint should be dismissed because it fails to satisfy minimum pleading standards set forth in the United States Supreme Court's decisions in *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007), and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009).

Recently, the Honorable Sandra J. Feuerstein granted a similar motion to dismiss filed by Boston Scientific and dismissed with prejudice a substantially similar complaint filed by the same counsel that represents Plaintiff in this action. *Oden v. Boston Scientific Corp.*, No. CV 18-0334 (SJF)(SIL), 2018 WL 3102534 (E.D.N.Y. June 4, 2018).[1] In *Oden*, Judge Feuerstein concluded:

[1] Following Judge Feuerstein's dismissal with prejudice, Plaintiff filed a motion for reconsideration, seeking leave to file an amended complaint. That motion remains pending.

- The design defect claim failed because the complaint neither (1) "allege[d] any *facts* indicating the particular component that was defective or otherwise identif[ied] a specific problem with the Greenfield Filter," nor (2) set forth a reasonable alternative design because "based on Plaintiff's own allegations, the Greenfield Filter, which is a permanent filter, is not comparable to a retrievable filter, since the design and purpose of these two products is different." *Id.* at *5 (emphasis in original).

- The manufacturing defect claim failed because the plaintiff did not "allege a *specific* manufacturing defect [that] affect[ed] the Greenfield Filter implanted in Plaintiff as compared to other Greenfield Filters that were produced" by Boston Scientific. *Id.* (emphasis in original).

- The failure-to-warn claim failed because the plaintiff neither (1) alleged "facts [that] set[] forth what the warnings stated and how and/or why the warnings were inadequate" nor (2) pleaded "any nonconclusory allegations that Plaintiff's treating physician was not adequately informed or apprised of the potential risks associated with the Greenfield Filter." *Id.* at *7.

- The express warranty claim failed because the plaintiff only alleged "purported 'reliance' without providing any underlying factual details concerning when, where and how such reliance arose." *Id.* at *9.

- The implied warranty of merchantability claim failed because the plaintiff did not "plead the necessary predicate elements to support his design and manufacturing defect claims." *Id.* at *9.

- The implied warranty of fitness claim failed because the complaint did not allege that Boston Scientific "was made aware of the *particular purpose* for which Plaintiff purchased the Greenfield Filter." *Id.* at *10 (emphasis in original).

- All fraud claims fell short of "the specificity required by Rule 9(b)." *Id.* at *13.

- The claim premised upon Sections 349 and 350 of the GBL did not adequately allege causation because Plaintiff failed to "explicitly state []or permit the plausible inference that Plaintiff actually saw these statements [in the brochure and webpages] prior to . . . purchas[ing] the Greenfield Filter." *Id.* at *14.

Judge Feuerstein's rationale in dismissing *Oden* is directly applicable here and the Amended Complaint should be dismissed in its entirety and with prejudice for the same reasons.[2]

[2] For the sake of completeness, we include citations to all other recent decisions in Greenfield Filter product liability cases filed against Boston Scientific by the same counsel that represents Plaintiff in this action. *Kendall v. Boston Scientific Corp.*, No. 6:17-cv-1888-Orl-37GJK, 2017

BACKGROUND[3]

A. Procedural History

On October 5, 2017, Plaintiff filed her original complaint in the Supreme Court of the State of New York, Queens County. Dkt. #1. Boston Scientific removed the action to this Court on November 9, 2017. *Id.* On November 16, 2017, Boston Scientific filed a letter seeking a pre-motion conference, explaining that Plaintiff's "prolix, yet uninformative, Complaint consists of legal conclusions and is devoid of factual content to support the alleged claims." Dkt. #4. Following discussion of these pleading deficiencies at a February 6, 2018, pre-motion conference (Dkt. #7), Plaintiff filed an Amended Complaint on March 9, 2018. In response, Boston Scientific filed a March 23, 2018, letter seeking a second pre-motion conference, stating that the

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WL 6042020 (M.D. Fla. Dec. 6, 2017) (dismissing original complaint without prejudice as impermissible shotgun pleading); *Douse v. Boston Scientific Corp.*, No. 2:17-cv-599-FtM-38MRM (M.D. Fla. Dec. 18, 2017) (same); *Davis v. Boston Scientific Corp.*, No. 2:17-cv-682-FtM-38CM, 2018 WL 339937 (M.D. Fla. Jan. 9, 2018) (same); *Parks v. Boston Scientific Corp.*, No. 5:17-cv-200, 2018 WL 1040103 (W.D.N.C. Feb. 23, 2018) (holding that "the substantive claims in the 42-page Complaint violate Rule 8(a)"); *Winkler v. Boston Scientific Corp.*, No. 5:17-274-KKC, 2018 WL 1474067 (E.D. Ky. Mar. 26, 2018) (dismissing all personal injury claims as time-barred, and all fraud and misrepresentation claims for failure to satisfy Rule 9(b)); *Kendall v. Boston Scientific Corp.*, No. 6:17-cv-1888-Orl-37GJK (M.D. Fla. Apr. 17, 2018) (dismissing amended complaint without prejudice breach of warranty, fraud and misrepresentation, and consumer protection claims for failure to satisfy Rules 8(a) and 9(b)); *Davis v. Boston Scientific Corp.*, No. 2:17-cv-682-FtM-38CM (M.D. Fla. May 11, 2018) (same); *Douse v. Boston Scientific Corp.*, No. 2:17-cv-599-FtM-38MRM (M.D. Fla. May 14, 2018) (same); *Tyler v. Boston Scientific Corp.*, No. 1:17-cv-09170, 2018 WL 2220531 (N.D Ill. May 15, 2018) (dismissing without prejudice failure to warn, breach of warranty, fraud and misrepresentation, and consumer protection claims for failure to satisfy Rules 8(a) and 9(b)); *Hepburn v. Boston Scientific Corp.*, No. 3:17-cv-00530-DCN, 2018 WL 2275219 (D. Idaho May 17, 2018) (dismissing with prejudice breach of warranty, fraudulent concealment, and negligent misrepresentation claims, and dismissing without prejudice fraud claims); *Douse v. Boston Scientific Corp.*, 2:17-cv-599-FtM-38MRM, 2018 WL 3536080 (M.D. Fla. July 23, 2018) (dismissing with prejudice fraudulent misrepresentation, fraudulent concealment, and negligent misrepresentation claims for failure to satisfy Rule 9(b)); *Davis v. Boston Scientific Corp.*, 2:17-cv-00682-SPC-CM, 2018 WL 3155683 (M.D. Fla. June 28, 2018) (same); *Kendall v. Boston Scientific Corp.*, 6:17-cv-1888-Orl-37-GJK, 2018 WL 3343239 (M.D. Fla. June 25, 2018) (same).

[3] Plaintiff's allegations are taken as true solely for purposes of this motion. References to "¶ __" are to paragraphs of the Amended Complaint, which is attached as Ex. A to the Declaration of Angela R. Vicari, dated August 10, 2018 (the "Vicari Declaration"). References to "Ex. __" are to the exhibits attached to the Vicari Declaration.

Amended Complaint "fails to remedy the pleading deficiencies that pervaded her original Complaint." Dkt. #10. Following a July 26, 2018, pre-motion conference, at which the parties an the Court discussed these pleading deficiencies, as well as Judge Feuerstein's order in *Oden v. Boston Scientific Corporation*, Plaintiff elected not to amend the Amended Complaint. Dkt. #17. As a result, the Court set a briefing schedule for Boston Scientific's motion to dismiss. *Id.*

B. Plaintiff's Amended Complaint

1. The Greenfield Filter

The inferior vena cava ("IVC") is a vein that "returns blood to the heart from the lower extremities." ¶ 26. Blood clots that develop in the leg and pelvis can travel from blood vessels in the leg and pelvis through the IVC and into the lungs, causing a pulmonary embolism ("PE"). *Id.* Clots that develop "in the deep leg veins" are referred to as "deep vein thrombosis" or "DVT." *Id.* "Individuals who are at risk of clotting are often treated with anticoagulants such as Heparin, Warfarin, or Lovenox to reduce the risk." ¶ 27. However, because anticoagulants are contraindicated for certain patients, doctors may recommend an IVC filter. ¶ 28. An IVC filter is not a cure for DVT. Rather, an IVC filter is "designed to prevent blood clots from traveling from the lower extremities to the heart and lungs. It is inserted into the IVC and works by trapping and filtering clots that form in the lower portions of the body." ¶ 29.

The Greenfield Filter is an IVC filter manufactured by Boston Scientific. It has been on the market since the 1970s. ¶ 30. Unlike certain filters that are "optional" or "retrievable," it is a *permanent* IVC filter—*i.e.*, it is not designed to be retrieved and has no retrieval option once implanted in a patient. ¶¶ 30, 31, 43, 44. Plaintiff does not allege whether she was implanted with a titanium or stainless steel Greenfield Filter, but the Directions for Use ("DFU") for both clearly indicate that the Greenfield Filter is "a permanently implanted [stainless steel/titanium] device designed to protect against pulmonary embolism while maintaining patency of the inferior

vena cava." Ex. B at 5; Ex. C at 4. Because it is a permanent filter, its design makes it different from the retrievable filters that began to gain FDA approval in the early 2000s. ¶ 44. Plaintiff alleges that unlike the Greenfield Filter, retrievable filters are "designed to be removed from a patient when the risk of PE/DVT has passed. Retrievable IVC filters were not designed to remain inside the IVC indefinitely." *Id.*[4]

The Greenfield Filter DFUs also list potential complications including: "migration of the Filter," "[f]ormation of clots on the Filter which could result in complete blockage of blood flow through the vena cava," "[p]erforation of the vena cava, adjacent blood vessels or organ by one

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[4] The Amended Complaint references two FDA Safety Alerts issued in 2010 and 2014 and various medical journal articles regarding IVC filters. ¶¶ 45-51, 53,55-57, 60. Although not relevant for purposes of this motion, Boston Scientific vigorously contests Plaintiff's characterization of those alerts and articles and the extent to which they apply to the Greenfield Filter. For example, the Amended Complaint includes the following selective and grossly misleading excerpt from the FDA's August 2014 FDA Safety Alert.

> The FDA encourages all physicians involved in the treatment and follow-up of patients receiving IVC filters to consider the risks and benefits of filter removal for each patient. A patient should be referred for IVC filter removal when the risk/benefit profile favors removal and the procedure is feasible given the patient's health status.

¶ 49. Plaintiff claims "it was clear in the warning when the FDA was warning particularly on retrievable filters and when they addressed IVC filters which included permanent filters," and that "[d]espite the FDA alerts in 2010 and 2014 advising of the risks of long-term implantation" Boston Scientific "continued to market its Greenfield IVC Filter for long-term use." ¶¶ 50-51. This allegation finds no support in any of the documents cited in the Amended Complaint—the FDA has never requested that Boston Scientific stop manufacturing the Greenfield Filter. Moreover, the paragraph in the 2014 Safety Alert that precedes the one quoted by Plaintiff makes clear that the FDA's recommendation applies to optional and retrievable filters and not permanent filters like the Greenfield Filter. *See* Ex. D at 1 ("The FDA recommends that implanting physicians and clinicians responsible for the ongoing care of patients with *retrievable* IVC filters consider removing the filter as soon as protection from pulmonary embolism is no longer needed.") (emphasis added). The Amended Complaint is replete with similar distortions of fact that will be rebutted should the Amended Complaint survive dismissal. For example, the medical journal articles referenced in the Amended Complaint lack any connection to Plaintiff's injuries or the Greenfield Filter. *See* ¶¶ 53-57 (referencing retrievable and/or permanent filters or IVC filters generally).

or more hooks," "pulmonary embolism," and "[d]eath due to movement of clots to the heart or lungs." *See* Ex. B at 9; Ex. C at 8.

2. Plaintiff's Allegations

Plaintiff alleges that on September 26, 2008, she was hospitalized for DVT and was implanted with a Greenfield Filter at North Shore University Hospital in Manhasset, New York. ¶¶ 61-62. Although Plaintiff alleges that she was implanted with a Greenfield Filter to "prevent further DVT in her lower extremity," she concedes in other paragraphs of the Amended Complaint that, consistent with the Greenfield Filter's Directions For Use, the purpose of an IVC filter is to prevent PE, not to prevent DVT. ¶¶ 29, 61. The Amended Complaint lacks any allegation that Plaintiff's Greenfield Filter failed to protect her from a pulmonary embolism. Instead, Plaintiff alleges that "[o]n November 9, 2017, Plaintiff underwent radiological examination (CT Scan of Abdomen without Contrast), where her Greenfield IVC Filter was found to be fractured, bent, migrated, and perforated through human tissue." ¶ 69. She further alleges that "[a]s a direct and proximate result of the Greenfield IVC Filter, Plaintiff has suffered serious personal injuries including but not limited to: recurrent DVTs; constant pain in the abdominal region; tilting, fracture, perforation, and migration of the Greenfield IVC Filter." ¶ 80.

ARGUMENT

I. THE AMENDED COMPLAINT FAILS TO ALLEGE "PLAUSIBLE" CLAIMS

A complaint must contain enough factual allegations to provide "'fair notice' of the nature of the claim" and the "'grounds' on which the claim rests." *Twombly*, 550 U.S. at 555 n.3. A complaint must be dismissed if it does not "contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 570). "A claim has facial plausibility when the plaintiff pleads *factual*

content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (emphasis added). Thus, a plaintiff must establish "more than a sheer possibility that a defendant has acted unlawfully." *Iqbal*, 556 U.S. at 678. "[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not show[n]—that the pleader is entitled to relief." *Iqbal*, 556 U.S. at 679; *Twombly*, 550 U.S. at 555 ("Factual allegations must be enough to raise a right to relief above the speculative level"). Mere "labels and conclusions" or "a formulaic recitation of the elements of a cause of action" are insufficient. *Iqbal*, 556 U.S. at 678 (citations and internal quotation marks omitted).

Pursuant to this authority, federal District Courts in New York routinely dismiss complaints in products liability actions that contain nothing more than speculation, conclusory statements and threadbare recitals of the elements of causes of actions.[5] Plaintiff's claims are subject to the same fate.

A. Plaintiff Fails to State a Plausible Claim for Strict Liability

Under New York's approach to products liability, a product has a defect that renders the manufacturer strictly liable for the resulting injuries if it contains a: "(1) design defect[]; (2) manufacturing defect[]; [or] (3) [a] defective or inadequate warning[]." *Oden,* 2018 WL

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[5] *See, e.g.*, *Oden*, 2018 WL 3102534; *Rincon v. Covidien*, No. 16-cv-10033(JMF), 2017 WL 2242969 (S.D.N.Y. May 22, 2017); *Adams v. Stryker Orthopaedics*, No. 15-cv-7098(VB), 2016 WL 2993213 (S.D.N.Y. May 23, 2016); *Ortiz v. Allergan, Inc.*, No. 14-civ-8188(PAC), 2015 WL 5178402 (S.D.N.Y. Sept. 4, 2015); *Rodman v. Stryker Sales Corp.*, No. 14-cv-1102(JMF), 2014 WL 5002095 (S.D.N.Y. Oct. 7, 2014), *aff'd* 604 Fed. Appx. 81 (2d Cir. May 21, 2015); *Bertini v. Smith & Nephew, Inc.*, 13 Civ. 0079(BMC), 2013 WL 6332684 (E.D.N.Y. July 15, 2013); *Goldin v. Smith & Nephew, Inc.*, No. 12 Civ. 9217(JPO), 2013 WL 1759575 (S.D.N.Y. Apr. 24, 2013); *Reed v. Pfizer, Inc.*, 839 F. Supp.2d 571 (E.D.N.Y. 2012); *Am. Guar. & Liab. Ins. Co. v. Cirrus Design Corp.*, No. 09 Cv. 8357 (BSJ)(HBP), 2010 WL 5480775 (S.D.N.Y. Dec. 30, 2010); *Gelber v. Stryker Corp.*, 752 F. Supp.2d 328 (S.D.N.Y. 2010); *Ilarraza v. Medtronic, Inc.*, 677 F. Supp.2d 582 (E.D.N.Y. 2009); *Lewis v. Abbott Labs.*, No. 08 Civ. 7480(SCR)(GAY), 2009 WL 2231701 (S.D.N.Y. July 24, 2009); *Horowitz v. Stryker Corp.*, 613 F. Supp.2d 271 (E.D.N.Y. 2009).

3102534, at *4; *see also In re N.Y. City Asbestos Litig.*, 27 N.Y.3d 765, 787, 59 N.E.3d 458, 469, 37 N.Y.S.3d 723, 734 (N.Y. 2016) (quoting *Liriano v. Hobart Corp.*, 92 N.Y.2d 232, 237, 700 N.E.2d 303, 305, 677 N.Y.S.2d 764, 766 (N.Y. 1998)). The Amended Complaint does not plausibly allege any defect.

1. Design Defect

A design defect claim is premised on an assertion that the manufacturer failed to properly design the product, and that the product was placed on the market, despite its inherent risks. *Voss v. Black & Decker Mfg. Co.*, 59 N.Y.2d 102, 107, 450 N.E. 2d 204, 207, 463 N.Y.S. 2d 398, 401 (N.Y. 1983). In order to plead a defective design claim under New York law, a plaintiff must show that "(1) the product as designed posed a substantial likelihood of harm; (2) it was feasible to design the product in a safer manner; and (3) the defective design was a substantial factor in causing plaintiff's injury." *Oden*, 2018 WL 3102534, at *4; *Bertini*, 8 F. Supp. 3d at 254.

Plaintiff does not allege any facts supporting a plausible design defect claim for two reasons. First, Plaintiff does not allege "any *facts* indicating the particular component that was defective or . . . identify[] a specific problem with [her] Greenfield Filter." *Oden*, 2018 WL 3102534, at *4 (emphasis in original). Instead, Plaintiff declares that the product was "unreasonably dangerous" and that the "unreasonable risk of serious harm" from the Greenfield Filter renders Boston Scientific "strictly liable for [her] injuries and damages sustained proximately caused by [her] use of the product." ¶¶ 102, 107,112. And although the Amended Complaint references the Greenfield Filter's "[r]ecurved hooks," which she claims "are designed to provide protection against penetration," (¶ 155), Plaintiff fails to allege that the recurved hooks constitute a defect. Nor does she allege injury as a result of the Greenfield Filter's recurved hooks. The Amended Complaint also refers to the Greenfield Filter as a "long-term"

implant, (¶ 71), but similarly fails to allege that the permanent nature of the device constitutes a defect. Nor could she. The fact that the Greenfield filter is "intended for long-term use" and "is marketed and sold as a permanent filter" cannot constitute a design defect under New York law. ¶¶ 33-34. The product is what it is—a permanent filter that does not have a retrieval option. The design defect claim must therefore be dismissed.[6]

Second, Plaintiff's "design defect claim also fails on the independent ground that the [Amended] Complaint does not plead the existence of a feasible alternative design," as required under New York law. *Oden*, 2018 WL 3102534, at *5; *Voss*, 59 N.Y.2d at 108. Since the Supreme Court's decisions in *Twombly* and *Iqbal*, District Courts in the Second Circuit have dismissed product liability cases on the pleadings where plaintiffs fail to identify a feasible alternative design. *See*, *e.g.*, *Oden*, 2018 WL 3102534, at *5; *Reed*, 839 F. Supp. 2d at 578 (dismissing design defect claim because plaintiffs did not "plead facts alleging the existence of a feasible alternative design that would make the product safer"); *Am. Guar. & Liab. Ins. Co.*, 2010 WL 5480775, at *3 (dismissing design defect claim where plaintiffs did not make "any mention of a feasible alternative design"); *Lewis*, 2009 WL 2231701, at *4 (dismissing design defect claim because plaintiff failed to allege "that it was feasible for [the defendant] to design

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[6] *Rincon*, 2017 WL 2242969, at *2 (dismissing design defect claim where plaintiff did not "identify any actual defect in the coating" in the device at issue and said "nothing about *how* the coating, even if defective, caused [her] specific injuries"); *Adams*, 2016 WL 2993213, at *2 (dismissing design defect claim where plaintiff failed to allege "(i) a problem with the metal plate that may have rendered it defective, (ii) whether a defect affected his individual metal plate, or (iii) how a defect caused his injuries"); *Rodman*, 604 Fed.Appx. at 82 (affirming dismissal of design defect claim because plaintiff never identified how "the application of the [device's] coating . . . rendered the product defective, whether it affected his individual hip replacement, or how it caused his alleged injuries"); *Goldin*, 2013 WL 1759575, at *4 (dismissing design defect claim because, *inter alia*, plaintiff merely "state[d] that the product poses a risk of harm because of its propensity to dislocate, but [did] not identify any particular problem in the design of the product"); *Reed*, 839 F. Supp. 2d at 577 (dismissing design defect claim where plaintiffs "merely [pled] the legal conclusion that [the drug] was defective"); *Lewis*, 2009 WL 2231701, at *4 (dismissing design defect claim where plaintiff alleged in "conclusory" fashion a drug was "inherently dangerous" and that "the negative consequences . . . outweigh the benefits the drug offers").

Depakote in a safer manner"). Here, Plaintiff does not identify an alternative design; nor has she alleged any facts to demonstrate that it was feasible to design the Greenfield Filter in a manner that would have prevented her injuries.

Any attempt by Plaintiff to identify the retrievable or optional filters referred to in the Amended Complaint as feasible alternative designs must fail because "based upon Plaintiff's own allegations, the Greenfield Filter, which is a permanent filter, is not comparable to a retrievable filter, since the design and purpose of these two products is different." *Oden*, 2018 WL 3102534, at *5. Under New York law, a safer alternative design must be one for the product at issue, not a different product. *Adamo v. Brown & Williamson Tobacco Corp.*, 11 N.Y.3d 545, 551 (2008) (no alternative design where "plaintiffs failed to show that light cigarettes are equivalent in function, or utility, to regular ones"); *Hilaire v. DeWalt Indus. Tool Co.*, 54 F. Supp. 3d 223, 248 (E.D.N.Y. 2014) ("A plaintiff cannot satisfy his burden to propose a feasible alternative design by proposing that an entirely different product could have been used"); *Simon v. Smith & Nephew, Inc.*, 990 F. Supp. 2d 395, 405 (S.D.N.Y. 2014) ("an allegation that Smith & Nephew could have manufactured a different product altogether, or that others have done so, does not itself make out a plausible claim of a design defect"); *Goldin*, 2013 WL 1759575, at *5 ("the question is whether a safer alternative design for *this* product existed") (emphasis in original). As Judge Feuerstein found in dismissing the design defect claim in *Oden*, retrievable and optional filters cannot be the basis of a design defect claim in a case involving injuries alleged from the Greenfield Filter because *they are entirely different products*. *Oden*, 2018 WL 3102534, at *5 ("Plaintiff's attempt to allege that the retrievable filter represents a feasible design alternative is unavailing."). Indeed here, Plaintiff concedes that retrievable and optional filters are "problematic," have been the subject of FDA Safety Alerts, and thus have their own

risk profile. ¶¶ 44-57. Accordingly, "an allegation that [Boston Scientific] could have manufactured a different product altogether, or that others have done so, does not itself make out a plausible claim of design defect." *Simon*, 990 F. Supp. 2d at 405 (granting motion to dismiss). Dismissal of Plaintiff's design defect claim is therefore warranted.

2. Manufacturing Defect

The gravamen of a manufacturing defect claim is that the product at issue is defective because it "does not conform in some significant aspect to the intended design, nor does it conform to the great majority of products manufactured in accordance with that design." *Caprara v. Chrysler Corp.*, 52 N.Y.2d 114, 128, 417 N.E.2d 545, 552, 436 N.Y.S.2d 251, 258 (N.Y. 1981). To plead and prove a claim based on a manufacturing defect, the plaintiff must show that a specific product unit was defective as a result of "'some mishap in the manufacturing process itself, improper workmanship, or because defective materials were used in construction,' and that the defect was the cause of plaintiff s injury." *Horowitz*, 613 F. Supp. 2d at 283. A manufacturing defect claim should be dismissed if plaintiff has not alleged that "the particular [product] administered to her had a defect as compared to other samples of that [product]." *Reed v. Pfizer, Inc.*, 839 F. Supp. 2d 571, 577 (E.D.N.Y. 2012) (quotation marks and citations omitted).

Plaintiff's manufacturing defect claim cannot survive dismissal because she fails to identify "what the particular error in the manufacturing process was or, at the very least, what component or components of [her] Greenfield Filter deviated from [Boston Scientific's] manufacturing standards when compared with [] other Greenfield Filters." *Oden*, 2018 WL 3102534, at *5. Plaintiff alleges in a conclusory manner that her Greenfield Filter "contained a condition or conditions, which Defendant did not intend, at the time it left Defendant's control and possession," and that her injuries were "[a]s a result of the condition or these conditions" and

the "direct and proximate result of the Greenfield Filter's manufacturing defects." ¶¶ 119-121. Such bald legal conclusions fail to satisfy federal pleading standards. Her vague allegations are unavailing, as they do not indicate "how or why" her Greenfield Filter "differed from its design." *Reed*, 839 F. Supp. 2d at 577. Moreover, the notion that a manufacturing defect caused injury to the Plaintiff is "remote," particularly "in view of the long period of time during which the device at issue functioned without incident." *Ilarraza*, 677 F. Supp. 2d at 589. Accordingly, Plaintiff's manufacturing defect claim should be dismissed.

3. Failure to Warn

"Under New York law, a medical device manufacturer has a duty 'to warn of all potential dangers which it knows or should know, and must take such steps as are reasonably necessary to bring that knowledge to the attention of the medical profession.'" *Bertini*, 8 F. Supp. 3d at 256 (quoting *Figueroa v. Boston Scientific Corp.*, 254 F. Supp. 2d 361, 370 (S.D.N.Y. 2003)). To prevail on a failure to warn claim, a plaintiff must prove a manufacturer has a duty to warn against dangers resulting from foreseeable uses about which it knew or should have known, and that failure to do so was the proximate cause of the harm. *In re N.Y. City Asbestos Litig.*, 27 N.Y.3d 765, 59 N.E.3d 458, 37 N.Y.S.3d 723 (N.Y. 2016). Here, Plaintiff's warnings claim should be dismissed because the Amended Complaint (1) "fails to provide facts identifying how or why the included warnings were inadequate" and (2) does not contain "any nonconclusory allegations that Plaintiff's treating physician was not adequately informed or apprised of the potential risks associated with the Greenfield Filter." *Oden,* 2018 WL 3102534, at *7.

a. Plaintiff's Conclusory Allegations Fail to State a Claim for Failure to Warn

Conclusory assertions that a warning was inadequate do not satisfy federal pleading standards. *Id.* at *7. In *Oden*, the plaintiff alleged that Boston Scientific "failed to provide

sufficient warnings and instructions," that the Greenfield Filter's "product brochure differs from the instructions for use since it 'only provides limited information [concerning] possible complications from the use of the IVC filter,'" and "that 'Defendant's warnings page on their website which possibly reflects the warning given in their [instructions for use lists only] general complications and adverse events but . . . fails to address the full extent of complications [and] magnitude of risks involved with the IVC filter.'" *Id* at *6. Judge Feuerstein dismissed the warnings claim because the allegations lacked facts as to "how the warnings that were indisputably provided . . . were inadequate." *Id.* *7. Thus, the failure-to-warn claim was insufficiently pled because the plaintiff did not identify "what the warnings state[d] and how and/or why the warnings were inadequate." *Id.*

Here, as in *Oden*, Plaintiff "fails to plead facts establishing how or why the warning[s] provided w[ere] inadequate." *Id.* at *7. Rather, Plaintiff makes the following conclusory and bare bones allegations:

- "Defendant failed to provide sufficient warnings and instructions that would have put Plaintiff, Plaintiff's physicians, and the general public on notice of the dangers and adverse effects caused by implantation of the Greenfield IVC Filter." ¶ 77.
- "Defendant's brochure and instructions for use lacked any notable warnings or indication to the full extent of risks and hazards related to their product." ¶ 78.
- "The Greenfield IVC Filter was designed, manufactured, distributed, sold, an/or supplied by Defendant, and was marketed while defective due to the inadequate warnings, instructions, labeling, and/or inadequate testing in light of Defendant's knowledge of the product's failure and serious adverse events." ¶ 79.
- "Defendant failed to adequately warn the medical community and consumers of the defective product, including the Plaintiff and Plaintiff's healthcare providers, of the dangers and risk of harm associated with the use and administration of its Greenfield Filter." ¶ 135.
- "Defendant failed to state the full extent of ways in which product was not safe and the numerous side effects, of which Defendant had full knowledge and did not accurately or adequately warn." ¶¶ 194, 216.

Nowhere in the Amended Complaint does Plaintiff reference the warnings in the Greenfield Filter DFU. Her omission is telling, given that the DFU warns of "many of the same risks alleged in the [Amended] Complaint." *Oden*, 2018 WL WL 3102534, at*6; *see also* Ex. B at 9; Ex. C at 8.

Instead, she bases her failure-to-warn claim on (i) a "product brochure" on the Boston Scientific website,[7] which she contends is "different from" the Greenfield Filter DFU and "provides limited information," and (ii) the section of Boston Scientific's website that serves as the Greenfield Filter's splash page, which she contends "fails to state the full extent of ways in which [the] product was not safe." ¶¶ 143, 152, 157, 214, 215, 216.[8] Neither the brochure, nor the webpage, can serve as the basis of Plaintiff's failure-to-warn claim. Although Plaintiff references a Greenfield Filter "product brochure," she omits any reference to the "**WARNINGS**," "**PRECAUTIONS**," "**POTENTIAL ADVERSE EVENTS**," and "**CONTRAINDICATIONS**" that appear in bold in the brochure. *Oden*, 2018 WL 3102534, at*6 ("the product brochure contains a nearly identical section entitled 'Potential Adverse Events' which includes many of the same complications as set forth in the Instructions for Use"); *see* Ex. F at 2. Similarly, Plaintiff fails to include in her Amended Complaint the fact that "there is a clearly delineated link to a 'Key Resources' section [on the Greenfield Product webpage] which includes relevant 'Indications, Safety, and Warnings.'" *Oden*, 2018 WL 3102534, at*6 ; *see* Ex. G at 1. The Court therefore may refuse to credit Plaintiff's demonstrably false assertions that the Greenfield Filter product brochure or website lacked adequate warnings. *Oden*, 2018

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7 Available at http://www.bostonscientific.com/content/dam/bostonscientific/pi/portfolio-group/vena-cava-filters/greenfield/Greenfield%20VCF%20Sell%20Sheet%20(PI-25210-AC).pdf. A copy of the brochure is attached as Ex. F.

8 Available at http://www.bostonscientific.com/en-US/products/embolic-protection/greenfield-vena-cava-filter.html. A copy of the webpage is attached as Ex. G.

WL 3102534, at*3 ("these documents shall be considered in adjudication of the motion to the extent that they are relevant and material"); *Hirsch v. Arthur Andersen & Co.*, 72 F.3d 1085, 1095 (2d Cir. 1995) (rejecting "attenuated allegations" that "are contradicted both by . . . facts of which we may take judicial notice"); *see also In re MBIA, Inc. Sec. Litig.*, 700 F. Supp. 2d 566, 576 (S.D.N.Y. 2010) ("The Court need not accept as true any allegations that are contradicted by . . . materials amenable to judicial notice.").

Accordingly, Plaintiff's failure-to-warn claim should be dismissed because the Amended Complaint does not plausibly allege why the warnings provided in the Greenfield Filter DFU, the product brochure, and the webpage are inadequate. *Oden*, 2018 WL 3102534, at*6-8; *see Goldin*, 2013 WL 1759575, at *5 (dismissing failure-to-warn claim because, *inter alia*, plaintiff did not "identify the allegedly defective warnings, nor d[id] she allege facts in support of her claim that these warnings were, in fact, defective"); *Reed*, 839 F. Supp. 2d at 575 (dismissing failure-to-warn claim because the complaint recited legal conclusions instead of "facts indicating how the provided warnings were inadequate").

b. Plaintiff Does Not Plausibly Allege That Boston Scientific Failed To Warn Her Implanting Physician

New York employs the learned intermediary doctrine, pursuant to which, "[t]he physician acts as an 'informed intermediary' between the manufacturer and the patient; and, thus, the manufacturer's duty to caution against a drug's side effects is fulfilled by giving adequate warning through the prescribing physician, not directly to the patient." *Martin v. Hacker*, 83 N.Y. 2d 1, 9, 628 N.E.2d 1308, 1311, 607 N.Y.S. 2d 598, 602 (N.Y. 1993). Accordingly, the failure-to-warn claim must be dismissed to the extent that it is based on an alleged failure to warn the Plaintiff, the "public," "consumers," "healthcare providers," and the "medical community." *Oden*, 2018 WL 3102534, at*7 ("to the extent Plaintiff's failure to warn claim is

premised upon Defendant's alleged failure to warn 'consumers' . . . such a claim is not viable"); ¶¶ 77, 124,134, 135, 145.

The Amended Complaint's threadbare allegation that "no adequate warning was communicated to Plaintiff's physicians and/or healthcare providers" (*e.g.*, ¶¶ 139) do not save her failure-to-warn claim from dismissal because Plaintiff does not allege how the Greenfield Filter DFU failed to warn *her* implanting physician of the risks associated with the product; nor does the Amended Complaint connect the Greenfield Filter product brochure or information on the Boston Scientific website to her implanting physician in any way. Because the Amended Complaint includes no facts concerning what Plaintiff's implanting physician knew of the risks associated with the Greenfield Filter, the failure to warn claim must be dismissed. *See Oden*, 2018 WL 3102534, at*7 ("Plaintiff has pleaded no facts to suggest that [her] physician did not possess independent knowledge about the risks associated with use of the Greenfield Filter separate and apart from [] any such warnings.").

B. Plaintiff Fails to State a Plausible Negligence Claim

To state a claim for negligence under New York law, a plaintiff must show: (1) that the manufacturer owed plaintiff a duty to exercise reasonable care; (2) a breach of that duty by failure to use reasonable care so that a product is rendered defective, *i.e.*, reasonably certain to be dangerous; (3) that the defect was the proximate cause of the plaintiff's injury; and (4) loss or damage. *Bertini*, 8 F. Supp. 3d at 258. Here, Plaintiff alleges that Boston Scientific breached the duty of care by: (1) failing "to conduct adequate testing" of the Greenfield Filter, (2) "failing to establish an adequate quality assurance program used in the manufacturing of the Greenfield IVC Filter," (3) "failing to establish and maintain an adequate post-market surveillance

program," and (4) improperly promoting the Greenfield Filter. ¶¶ 91-92 (including subparts).[9] The negligence claim should be dismissed because Plaintiff does not allege any facts to support these conclusory assertions.

Bertini v. Smith & Nephew, Inc., No. 13 Civ. 0079 (BMC), 2013 WL 6332684 (E.D.N.Y. July 15, 2013) is instructive. In *Bertini*, plaintiffs supported their negligence claim by listing "ten different ways in which defendants allegedly breached their duty of reasonable care," such as: (1) "fail[ing] to conduct adequate post marketing surveillance," (2) "failing to make timely and adequate corrections to the manufacture, design and formulation of R3 liner so as to prevent and/or minimize the problems suffered by R3 liner use," and (3) "despite its knowledge [the product's risks], . . . continu[ing] to promote and market the R3 liner." *Id.* at *5. The court dismissed the negligence claims because these allegations were "boilerplate allegations from some form book" that plaintiffs failed to support "with any specific facts." *Id. See also In re Pamidronate Prods. Liab. Litig.*, 842 F. Supp. 2d 479, 484-485 (E.D.N.Y. Jan. 30, 2012) (dismissing negligence claim where plaintiff alleged that defendants "failed to exercise reasonable care in testing, manufacturing, labeling, marketing, distributing and selling" their drug, because these were merely conclusory allegations with no factual support).

Similarly, Plaintiff alleges no factual content as to how a vaguely alleged failure to test caused her alleged injury. She omits any factual allegations as to why Boston Scientific's quality

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[9] "Under New York law, a Plaintiff's claim based upon an alleged design defect or manufacturing defect sounding in either negligence or strict liability are functionally equivalent and will be analyzed concurrently." *Oden*, 2018 WL 3102534, at*4; *Goldin*, 2013 WL 1759575, at *6 (quoting *Pinello v. Andreas Stihl Ag & Co. KG*, No. 8:08-CV-00452 (LEK/RFT), 2011 WL 1302223, at *16 (N.D.N.Y. Mar. 31, 2011)) ("'New York courts generally consider strict products liability and negligence claims to be 'functionally synonymous.'"); *see also Martin*, 83 N.Y.2d at 8 n.1 ("[w]here liability is predicated on a failure to warn, New York views negligence and strict liability claims as equivalent") (citation omitted). Therefore to the extent that Plaintiff's negligence claims are based on alleged failure to warn or defective design or manufacture, such claims should be dismissed for the same reasons as her strict products liability claims. *See* section I.A., *supra*.

assurance systems and post-market surveillance programs were inadequate. And the allegation of improper promotion fails to identify any advertising or other statements by Boston Scientific that are alleged to have been improper, much less connect such statements to Plaintiff's implantation, her physician or her alleged injuries. Such threadbare recitals and conclusory declarations do not constitute "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 570). In any event, Plaintiff's inadequate testing claim must be dismissed because "'failure to test' is not a cognizable claim under New York products liability law." *Tuosto v. Philip Morris USA Inc.*, 672 F. Supp. 2d 350, 354 n. 2 (S.D.N.Y. 2009).

C. The Amended Complaint Fails to Allege Plausible Claims for Breach of Warranty

1. Express Warranty

A successful claim of a breach of express warranty requires proof that an express warranty existed, was breached, and that plaintiff had relied on that warranty. *Cavanagh v. Ford Motor Co.*, No. 13–CV–4584(JS)(WDW), 2014 WL 2048571, at *4 (E.D.N.Y. May 19, 2014). If a "[p]laintiff does not identify the terms of the purported warranty he claims to have relied on, any conclusory allegation . . . for breach of express warranty [must] be dismissed." *Id.* (quotations omitted). And, Plaintiff must describe how the representations were made and how she relied on them. *Horowitz*, 613 F. Supp. 2d at 286 (dismissing express warranty claim where plaintiff did not describe how representations were made or allege that he relied on defendants' alleged representations); *Surdo v. Stamina Prods., Inc.*, No. 15-CV-2532, 2015 WL 5918318, at *6 (E.D.N.Y. Oct. 9, 2015) (dismissing express warranty claim).

Plaintiff's express warranty claim should be dismissed because it fails to meet the requirements of such a claim under New York law. In support of her express warranty claim,

Plaintiff cites the Boston Scientific webpage and a Greenfield Filter product brochure discussed above. She appears to contend that the company warranted that: (i) the Greenfield Filter has "Trusted Performance, Timeless Design" (¶ 151), "Proven Stability" and "Established Filter Performance" (¶ 153), (ii) its design "Promotes Clot Lysis" (¶ 153), and (iii) the Greenfield Filter is "the most trusted and most likely to protect from adverse events" (¶ 154). However, the Amended Complaint fails to allege that either the Plaintiff or her implanting physician relied upon any of these representations. Nor does the Amended Complaint state how these statements formed the basis of the bargain. To the contrary, Plaintiff alleges that the brochure "might not be the same brochure given to Plaintiff at the time of her implant." ¶ 152. Absent any allegations connecting the supposed express warranties made by Boston Scientific to the Plaintiff, the express warranty claim should be dismissed. *Oden,* 2018 WL 3102534, at*9 (dismissing express warranty claim where plaintiff failed to plead facts that "[she] or [her] physicians relied on the statements set forth on [Boston Scientific's] website and/or product brochure"); *see also Goldin*, 2013 WL 1759575, at *6; *Horowitz*, 613 F. Supp. 2d at 286.

2. Implied Warranty

"'[L]iability under strict products liability and implied warranty theory are essentially the same.'" *Goldin*, 2013 WL 1759575, at * 5 (quoting *Pinello v. Andreas Stihl Ag & Co. KG,* No. 8-cv-452, 2011 WL 1302223, at *17 (N.D.N.Y. Mar. 31, 2011)). Accordingly, "[t]o succeed on an implied warranty claim, Plaintiff must establish: '(1) that the product was defectively designed or manufactured; (2) that the defect existed when the manufacturer delivered it to the purchaser or user; and (3) that the defect is the proximate cause of the accident.'" *Goldin*, 2013 WL 1759575, at *5 (quoting *Plemmons v. Steelcase Inc.*, No. 04 Civ. 4023(LAP), 2007 WL 950137, at *3 (S.D.N.Y. Mar. 29, 2007)). The breach of implied warranty causes of action in Plaintiff's Amended Complaint contain much of the same conclusory allegations set forth in the

claims for strict liability. ¶¶ 165-75. As with the other causes of action, Plaintiff never identifies the alleged defect or malfunction in her Greenfield Filter. She alleges no facts as to the manner in which the device failed or even which component of the device supposedly failed, let alone facts sufficient to support a theory that product defect caused the failure. These pleading inadequacies are fatal to Plaintiff's breach of implied warranty of merchantability claim. *Oden,* 2018 WL 3102534, at*9 (holding breach of implied warranty of merchantability claim "necessarily fails as a matter of law" where Plaintiff has not pled "sufficient factual allegations that the Greenfield Filter was defectively designed or manufactured"). Similarly, Plaintiff's blatant failure to "plead that [Boston Scientific] knew of a particular purpose for which Plaintiff purchased the Greenfield Filter or that Plaintiff and/or [her] physicians were relying upon [Boston Scientific's] specialized skill and judgment" dooms her implied warranty of fitness claim "as a matter of law." *Id.*

D. The Amended Complaint Fails to Allege Plausible Claims Under GBL §§ 349-350

GBL § 349 prohibits "[d]eceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in this state." GBL § 350 prohibits "[f]alse advertising in the conduct of any business, trade or commerce or in the furnishing of any service in this state." To assert a claim under either section, "a plaintiff must allege that a defendant has engaged in (1) consumer-oriented conduct that is (2) materially misleading and that (3) [the] plaintiff suffered injury as a result of the allegedly deceptive act or practice." *Orlander v. Staples, Inc.*, 802 F.3d 289, 300 (2d Cir. 2015) (citing *Koch v. Acker, Merrall & Condit Co.*, 18 N.Y.3d 940, 941, 967 N.E.2d 675, 944 N.Y.S.2d 452 (N.Y. 2012)); *see Maurizio v. Goldsmith*, 230 F.3d 518, 521 (2d Cir. 2000) (citing the elements for a prima facie case under GBL § 349).

Conclusory allegations will not suffice. To state a claim under GBL §§ 349 and 350, Plaintiff must not only identify the deceptive acts, but also how those acts caused her injury. For example, in *Oden*, Judge Feuerstein dismissed the plaintiff's claims under GBL §§ 349 and 350 because none of his allegations "provide[d] any indication that Plaintiff ever saw these statements and, to the extent he did, where, when and how Plaintiff came to view either the website or the product brochure." *Oden*, 2018 WL 3102534, at *14; *see also Horowitz*, 613 F. Supp. 2d at 287-88 (dismissing plaintiff's claims under GBL §§ 349 and 350 because she failed to allege a "connection between the defendants' deceptive conduct and a specific injury that she suffered as a result of that activity.").

The same defects are fatal to Plaintiff's GBL §§ 349 and 350 claims. To support her claims, Plaintiff sets forth nearly identical allegations to those alleged by the plaintiff in *Oden*:

- "The Defendant acted, used and employed unconscionable commercial practices, deception, fraud, false pretenses, false promises and misrepresentations, and knowingly concealed, suppressed and omitted material facts with the intent that consumers, including Plaintiff herein and Plaintiff's physicians and medical providers, rely upon such concealment, suppression and omission, in connection with sale, advertisement and promotion of the IVC filter in violation of all applicable state consumer fraud statutes, for the purpose of influencing and inducing physicians and medical providers to prescribe and implant the IVC filter into patients/consumers such as the Plaintiff herein." ¶ 241.

- "By reason of the Defendant's unconscionable, deceptive and fraudulent acts and practices, and false pretenses, false promises and misrepresentations, reasonable patients/consumers acting reasonably, such as the Plaintiff, herein, were caused to suffer ascertainable loss of money and property and actual damages." ¶ 242.

- "Defendant misrepresented and omitted material information regarding the subject product by failing to disclose known risks." ¶ 244.

- "Defendant's misrepresentations and concealment of material facts constitute unconscionable commercial practices, deception, fraud, false pretenses, misrepresentation, and/or the knowing concealment, suppression, or omission of materials facts with the intent that others rely on such concealment, suppression, or omission in connection with the sale and advertisement of the subject product, in violation of New York General Business Law ("GBL") §§ 349 and 350." ¶ 245.

- "The Defendant violated these statutes by knowingly and falsely representing that the subject product was fit to be used for the purpose for which it was intended, when the Defendant knew it was defective and dangerous, and by other acts alleged herein." ¶ 246.

- "The Defendant engaged in the deceptive acts and practices alleged herein in order to sell the subject product to the public, including Plaintiff." ¶ 247.

- "As a direct and proximate result of the Defendant's violations of GBL §349 and § 350, Plaintiff suffered damages, for which Plaintiff are entitled to compensatory damages, equitable and declaratory relief, punitive damages, costs and reasonable attorneys' fees." ¶ 248.

- "As a direct and proximate result of Defendant's conduct, the Plaintiff used the Greenfield IVC Filter and the Plaintiff suffered serious physical injury, and harm in addition to damages." ¶ 249.

The Amended Complaint "sets forth certain statements contained on [Boston Scientific's] website and in its product brochure . . . [but] these allegations neither explicitly state nor permit the plausible inference that Plaintiff actually saw these statements prior to making the determination (in conjunction with [her] physicians) to purchase the Greenfield Filter." *Oden*, 2018 WL 3102534, at *14. Accordingly, Plaintiff's claims under the GBL §§ 349 and 350 are "simply lacking" and must be dismissed. *Id.*

E. The Amended Complaint Fails to Adequately Allege Punitive Damages

Under New York Law, a claim for punitive damages is not "an independent basis of recovery." *Bowdrie v. Sun Pharm. Indus. Ltd.*, 909 F. Supp. 2d 179, 190 (E.D.N.Y. 2012). Since none of Plaintiff's substantive claims can survive a motion to dismiss, "there is no predicate cause of action that can serve as a viable basis for [her] punitive damages claim." *Oden*, 2018 WL 3102534, at *15. Thus, Plaintiff's claim for punitive damages must be dismissed.

II. PLAINTIFF'S CLAIMS OF FRAUD AND NEGLIGENT MISREPRESENTATION FAIL TO SATISFY FEDERAL RULE 9(b)

"[I]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). Plaintiff's fraudulent and negligent misrepresentation claims are subject to Rule 9(b)'s heightened pleading standards. *Bertini*, 8 F. Supp. 3d 246, 259 (fraudulent misrepresentation); *Aetna Cas. & Sur. Co. v. Aniero Concrete Co.*, 404 F.3d 566, 583 (2d Cir. 2005) (negligent misrepresentation). Thus, to survive dismissal, her Amended Complaint must: "(1) detail the statements (or omissions) that the plaintiff contends are fraudulent, (2) identify the speaker, (3) state where and when the statements (or omissions) were made, and (4) explain why the statements (or omissions) are fraudulent." *Harsco Corp. v. Segui*, 91 F.3d 337, 347 (2d Cir. 1996) (affirming dismissal of fraud and negligent misrepresentation claims); *see also Bullen v. Wells Fargo Home Mortg.*, No. 14-CV-3185 (NFR)(RLM), 2015 WL 1785579, at *2 (E.D.N.Y. Apr. 15, 2015) (dismissing fraud claims where plaintiff alleged "no facts explaining the circumstances of the allegations, such as content or time, to suggest Defendants engaged in fraud."); *Bertini*, 8 F. Supp. 3d at 259 (dismissing fraud claims for failing to satisfy Rule 9(b)). In other words, "Rule 9(b) requires a claimant to allege 'the who, what, where, when and why' of the claim." *Comfort Inn Oceanside v. Hertz Corp.*, No. 11-CV(JG)(JMA)-1534, 2011 WL 5238658, at *6 (E.D.N.Y. Nov. 1, 2011).

Here, the Amended Complaint is devoid of specifics regarding the who, what, where, and when of the fraud or misrepresentation that allegedly took place. Plaintiff fails to identify a single alleged representation made by Boston Scientific or explain who made the representation or why the representation was false. Also missing from the Amended Complaint are any fraudulent statements that Boston Scientific specifically made *to Plaintiff or her doctors* that were relied upon to her detriment. Plaintiff's fraud claim references the same Greenfield Filter

product brochure described *supra*, but Plaintiff fails to allege that she or her implanting physician ever saw the brochure. In fact, Plaintiff concedes that the "brochure might not be the same brochure given to Plaintiff at the time of her implant." ¶ 152. Therefore, Plaintiff fails to satisfy Federal Rule 9(b)'s heightened pleading requirements and her fraud claims must be dismissed. *Oden*, 2018 WL 3102534, at *10-13 (dismissing nearly identical fraud claims for failure to satisfy 9(b)).[10]

III. DISMISSAL *WITH* PREJUDICE IS WARRANTED

It is well settled that "leave to amend a complaint need not be granted when amendment would be futile." *Anderson v. Cty. of Nassau*, No. 15-CV-5351 (JMA) (AYS), 2018 WL 1597399, at *9 (E.D.N.Y. Mar. 31, 2018) (internal citations and quotations omitted). Moreover, an "amendment is 'futile' if the proposed pleading would not withstand a motion to dismiss." *Id.* Dismissal with prejudice is particularly warranted here because, as Plaintiff made evident at the pre-motion conference, there is no "indication that [s]he is in possession of facts that would cure the problems identified" in her Amended Complaint. *Curry v. Town of Islip*, No. 13-CV-3597 (JMA) (SIL), 2017 WL 6947742, at *4 (E.D.N.Y. Dec. 8, 2017) report and recommendation adopted, 2018 WL 437493 (E.D.N.Y. Jan. 12, 2018). Plaintiff has already amended her complaint once and has been made aware of its deficiencies by Boston Scientific, this Court, and through Judge Feuerstein's decision in *Oden*. There should be no third bite of the proverbial apple and the Amended Complaint should be dismissed with prejudice.

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[10] To date, all fraud-based claims subject to Rule 9(b) that have been filed by plaintiffs alleging injury as a result of a Greenfield Filter have been dismissed at the pleading stage. *See Parks*, 2018 WL 1040103 (W.D.N.C. Feb. 23, 2018); *Winkler*, 2018 WL 1474067 (E.D. Ky. Mar. 26, 2018); *Kendall*, No. 6:17-cv-1888-Orl-37GJK (M.D. Fla. Apr. 17, 2018); *Davis*, No. 2:17-cv-682-FtM-38CM (M.D. Fla. May 11, 2018); *Douse*, No. 2:17-cv-599-FtM-38MRM (M.D. Fla. May 14, 2018); *Tyler*, 2018 WL 2220531 (N.D Ill. May 15, 2018); *Hepburn*, 2018 WL 2275219 (D. Idaho May 17, 2018); *Douse*, 2018 WL 3536080 (M.D. Fla. July 23, 2018); *Davis*, 2018 WL 3155683 (M.D. Fla. June 28, 2018); *Kendall*, 2018 WL 3343239 (M.D. Fla. June 25, 2018).

CONCLUSION

For the reasons set forth above, Boston Scientific respectfully requests that the Amended Complaint be dismissed with prejudice.

Dated: New York, New York
August 10, 2018

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